(xxxiii) * * *

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Castor oil, hydrogenated polymer with ethylenediamine, 12-hydroxyoctadecanoic acid and sebacic acid (CAS Reg. No. 68604–06–8). The condensation product formed by the reaction of hydrogenated castor oil with polyamide derived from ethylenediamine, sebacic acid and 12-hydroxystearic acid, for use only in coatings at a level not to exceed 3.2 percent by weight of the resin when such coatings are intended for repeated use in contact with foods only of the types identified in paragraph (d) of this section, Table 1, under Types I, II, and III, under conditions of use C, D, E, or F as described in Table 2 of paragraph (d) of this section; or when such coatings are intended for repeated use in contact with foods of the types identified in paragraph (d) of this section, Table 1, under Types V, VI, VII, and VIII, under conditions of use E or F as described in Table 2 of paragraph (d) of this section. Use shall be limited to coatings for tanks of capacity greater than 530,000 gallons.

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Dated: September 6, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–23244 Filed 9–19–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 177

[Docket No. 92F–0237]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 1,1′-sulfonylbis[4-chlorobenzene] polymer with 4,4′-(1-methylethylidene)bis[phenol] (maximum 8 percent) and 4,4′-sulfonylbis[phenol] (minimum 92 percent) as repeat-use articles or components of repeat-use articles that contact food. This action is in response to a petition filed by BASF Corp.

DATES: Effective September 20, 1995; written objections and requests for a hearing by October 20, 1995. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication listed in § 177.2440, effective September 20, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 8, 1992 (57 FR 30224), FDA announced that a food additive petition (FAP 1B4263) had been filed by BASF Corp., 1609 Biddle Ave., Wyandotte, MI 48192–3799. The petition proposed to amend the food additive regulations in § 177.2440 *Polyethersulfone resins* (21 CFR 177.2440) to provide for the safe use of 1,1′-sulfonylbis[4-chlorobenzene] polymer with 4,4′-(1-methylethylidene)bis[phenol] (maximum 8 percent) and 4,4′-sulfonylbis[phenol] (minimum 92 percent) as repeat-use articles or components of repeat-use articles that contact food.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that the proposed use of the food additive is safe and that § 177.2440 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety

and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before October 20, 1995, file with the Dockets Management Branch (address above) written objection thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objection received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 177.2440 is amended by revising paragraphs (a) and (b) to read as follows:

§ 177.2440 Polyethersulfone resins.

* * * * *

(a) For the purpose of this section, polyethersulfone resins are:

(1) Poly(oxy-*p*-phenylenesulfonyl-*p*-phenylene) resins (CAS Reg. No. 25667–42–9), which have a minimum number average molecular weight of 16,000.

(2) 1,1′-sulfonylbis[4-chlorobenzene] polymer with 4,4′-(1-methylethylidene)bis[phenol] (maximum 8 percent) and 4,4′-sulfonylbis[phenol] (minimum 92 percent) (CAS Reg. No. 88285–91–0), which have a minimum number average molecular weight of 26,000.

(3) In paragraphs (a)(1) and (a)(2) of this section, the minimum number average molecular weight is determined by reduced viscosity in dimethyl formamide in accordance with ASTM method D2857–70 (Reapproved 1977), ''Standard Test Method for Dilute Solution Viscosity of Polymers,'' which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, 1110 Vermont Ave. NW., suite 1200, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(b) The basic resins identified in paragraphs (a)(1) and (a)(2) of this section may contain optional adjuvant substances described in § 174.5(d) of this chapter and the following:

List of substances	Limitations
Diphenylsulfone	Not to exceed 0.2 percent as residual solvent in the finished basic resin described in paragraph (a)(1) of this section.
Dimethyl sulfoxide .	Not to exceed 0.01 percent as residual solvent in the finished basic resin described in paragraph (a)(1) of this section.
N-methyl-2-pyrrolidone.	Not to exceed 0.01 percent as residual solvent in the finished basic resin described in paragraph (a)(2) of this section.

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Dated: September 6, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–23248 Filed 9–19–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Flunixin Meglumine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Fort Dodge Laboratories. The ANADA provides for intravenous or intramuscular use of flunixin meglumine injection for alleviation of inflammation and pain associated with musculoskeletal disorders and visceral pain associated with colic in horses.

EFFECTIVE DATE: September 20, 1995.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Fort Dodge Laboratories, 800 Fifth St. NW., P.O. Box 518, Fort Dodge, IA 50501, filed ANADA 200–142, which provides for intravenous or intramuscular use of flunixin meglumine injection for alleviation of inflammation and pain associated with musculoskeletal disorders and visceral pain associated with colic in horses.

ANADA 200–142 for Fort Dodge's flunixin meglumine injection is approved as a generic copy of Banamine® (flunixin meglumine) Injection in Schering-Plough's NADA 101–479. The ANADA is approved as of August 18, 1995, and the regulations are amended in 21 CFR 522.970(b) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.970 is amended by revising paragraph (b) to read as follows:

§ 522.970 Flunixin meglumine solution.

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(b) *Sponsors.* See Nos. 000061 and 000856 in § 510.600(c) of this chapter.

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Dated: September 5, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–23245 Filed 9–19–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Pharmaceutical, Inc. The ANADA provides for intravenous use of oxytetracycline hydrochloride injection in cattle for treatment of certain diseases caused by pathogens sensitive to oxytetracycline.

EFFECTIVE DATE: September 20, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center For Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Phoenix Pharmaceutical, Inc., 4621 Easton Rd., P.O. Box 6457 Farleigh Station, St. Joseph, MO 64506–0457, filed ANADA 200–068, which provides for intravenous use of oxytetracycline hydrochloride injection in cattle for the treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp., bacterial enteritis (scours) caused by *Escherichia coli*, necrotic pododermatitis (foot rot) and calf diphtheria caused by *Spherophorus necrophorus*, wooden tongue caused by *Actinobacillu lignieresii*, wound infection and traumatic injury caused by oxytetracycline susceptible strains of streptococcal and staphylococcal bacteria.

Phoenix Pharmaceutical, Inc.'s, ANADA 200–068 for oxytetracycline hydrochloride injection is approved as a generic copy of Fermenta's NADA 108–963 for Medamycin®-100. The ANADA is approved as of July 31, 1995, and the regulations are amended in 21 CFR 522.1662a(h) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of